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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/646,682

08/22/2003

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EXAMINER

DEJONG, ERIC S

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/646,682

Applicant(s)

FERNANDEZ, DENNIS S.

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006 and 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/01/2006 and 06/21/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED OFFICE ACTION

This application has been transferred to a new examiner.

Claims 1-35 are canceled. Claims 36-43 are newly presented and currently under examination. For clarity of the record, it is noted that the invention and limitations recited in original claims 2-5 and 7-10, now canceled, are identical to the invention and limitations now recited in newly presented claims 36-43, respectively.

Information Disclosure Statement

Information Disclosure Statements (IDS) filed 09/01/2006 and 06/21/2007 been considered in full.

Specification

The objection to the disclosure for containing an embedded hyperlink and/or other form of browser-executable code is withdrawn in view of the amendments made to the specification filed 09/01/2006.

Claim Rejections - 35 USC § 112, First Paragraph

The rejection of claims 2-5 and 7-10 (now presented as claims 36-43, respectively) under rejected under 35 U.S.C. 112, first paragraph, as failing to comply

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with the enablement requirement is withdrawn in view of arguments presented by applicants.

Claim Rejections - 35 USC § 112, Second Paragraph

The previous rejection of claims 2-5 and 7-10 (now presented as claims 36-43, respectively) is withdrawn in view of arguments presented by applicants.

Instant claims 36-39 have been broadly interpreted as reading on an apparatus comprising an integrated biosensor and simulation system. Further, the limitations recited in claims 36-39 are treated as limiting the function of the integrated biosensor and simulation system structure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is newly applied.

Regarding product and process in the same claim, MPEP 2173.05(p) states:

"A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. In *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph. Such claims should also be rejected under 35 U.S.C. 101 based in that the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. *Id.* at 1551."

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The preamble of claim 40 recites "Automated sensor and simulation method" in line 1 of said claim, which embraces both statutory classes of an apparatus and process. Further, claim 40 recites the apparatus limitations of "said sensor" and "said simulator" in lines 3 and 4 and process limitations directed to a method of their use. Thus, the instant claim is directed to neither a process or apparatus, but rather encompasses two different or overlapping statutory classes of invention as set forth in 35 USC § 101 and is therefore indefinite under 35 § USC 112, second paragraph. Claims 41-43 are also included under this rejection due to their dependence from claim 40.

Claim 40 recites the limitation "said simulator" in line 3. Similarly, claim 41 recites the limitation "the simulator" in line 2. There is insufficient antecedent basis for these limitation in the instant claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 40-43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection is newly applied.

Regarding product and process in the same claim, MPEP 2173.05(p) states:

"A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. In *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph. Such claims should also be rejected under 35 U.S.C. 101 based in that the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different

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statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. *Id.* at 1551.”

The preamble of claim 40 recites “Automated sensor and simulation method” in line 1 of said claim, which embraces both statutory classes of an apparatus and process. Further, claim 40 recites the apparatus limitations of “said sensor” and “said simulator” in lines 3 and 4 and process limitations directed to a method of their use. Therefore, the instant claim is properly rejected under 35 USC § 101 as it is directed to neither a process or apparatus, but rather encompasses two different or overlapping statutory classes of invention as set forth in 35 USC § 101, which is drafted so as to set forth the statutory classes of invention in the alternative only. Claims 41-43 are also included under this rejection due to their dependence from claim 40.

Claim Rejections - 35 USC § 102

The rejection of claims 2, 4, 5, 7, 9, and 10 (now presented as claims 36, 38-40, 42, and 43, respectively) under 35 U.S.C. § 102(b) as being anticipated by Grass et al. (US Patent 6,542,858) is withdrawn in view of arguments presented by applicants.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36- 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Giuffre (US Patent 6,042,548). The rejection of 36, 38-40, 42, and 43 (previously

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presented as claims 2, 4, 5, 7, 9, and 10) is maintained from the Office action mailed 05/18/2006. This rejection is newly applied against claims 37 and 41.

The instant claims are drawn to an integrated biosensor and simulation system and a method of use. The system comprises a sensor, a simulator, wherein said simulator is reconfigurable by said simulator. The related method of use comprises the steps of sensing a biological target to generate a signal, simulating using said signal and a model of the biological target to generate a therapeutic or diagnostic output.

Guiffre discloses a method and a system for registering changes in brain and central nervous system activity by using simulation and signals derived from biosensors (e.g., cardiovascular signal) (See Guiffre, Abstract, col. 4, lines 6-17, and claims 1, 5, 7, 8, 12, and 18). Guiffre discloses generating a signal of a biological target by a biosensor (col. 9, lines 26-37), which reads on a sensor, as recited in claims 36 and 40, and the process step of sensing a biological target to generate a signal, as recited in claim 40. Guiffre discloses computer systems for simulation of brain activity using a signal data and a model to estimate brain and central nervous system activity (see Guiffre, col. 4, line 6 through col. 5, line 11), which reads on a simulator, as recited in claims 36 and 40, and the process step of simulating using the signal and a model of the target to generate a therapeutic or diagnostic output, as recited in claim 40. Guiffre discloses embodiments of trained neural net and self-teaching computer systems that act in real-time to incrementally perturb a system and/or change models until data management is optimal (see Guiffre, Fig 3., col. 4, lines 6-60 and col. 6, lines 53-59), which reads on a

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sensor reconfigurable by a simulator, as recited in claims 36 and 40, and the process step of a simulator reconfiguring a sensor, as recited in claim 40.

Guiffre further teaches the detection of drug infusions and drug and alcohol levels in the blood for use in the disclosed method and a system for registering changes in brain and central nervous system activity (see Guiffre, col. 7, line 44 through col 8, line 2), which reads on a sensor that senses a food material for consumption by a biological target, the generation of a second signal therefrom, and the use of said second signal to generate a therapeutic or diagnostic output as recited claims 37 and 41. Guiffre teaches generating an output according to a regulatory condition by the disclosed simulation system (see Guiffre, col. 7, line 44 through col. 8, line 24), as recited in claims 38 and 42. Guiffre discloses coupling using a trained neural net and self-teaching computer systems (a switch) (see Guiffre, Figs. 1-3 and col. 4, lines 6-60), which reads on a sensor coupled to a simulator via a programmable switch as recited in claims 39 and 43.

Claim Rejections - 35 USC § 103

The previous rejection of claims 3 and 8 (now presented as claims 37 and 41, respectively) under 35 UCS §103(a) as being unpatentable over Grass et al. (US Patent 6,542,858) in view of Quellette (see citation No. 20 of the IDS filed 08/22/2003; *The Industrial Physics*, pages 11-12, 1998) is withdrawn in view of arguments presented by applicants.

Response to Arguments

Applicant's arguments filed 05/29/2007 have been fully considered but they are not persuasive.

In regards to the rejection of claims under 35 USC 102(b) as being anticipated by Guiffre, applicants argue that the reference does not disclose a sensor that is reconfigured by a simulator.

Applicants argument is not persuasive. It is reiterated from the above rejection that Guiffre discloses embodiments of trained neural net and self-teaching computer systems that act in real-time to incrementally perturb a system and/or change models until data management is optimal (see Guiffre, Fig 3., col. 4, lines 6-60 and col. 6, lines 53-59). Contrary to applicants argument, the trained neural net/self-teaching computer systems (a simulator), as taught by Guiffre, interact with a biological target to induce perturbations which are then detected by biosensors (reconfiguring of a sensor).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shukla Ram can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric S DeJong
Examiner
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08/03/2007